REMARKS

By way of summary, Claims 1-17 were pending in this application. In this paper, Claims 1, 2, 4, and 6-9 have been amended, Claims 3 and 5 have been canceled, and Claims 18-35 have been added. Accordingly, Claims 1, 2, 4, and 6-35 are pending for consideration.

Claims 1, 2, and 9 Are Patentably Distinguished Over Runge

Claims 1, 2, and 9 are rejected in the Office Action as being anticipated under 35 U.S.C. § 102(b) as being anticipated by Runge (U.S. Patent No. 5,785,686). Although Applicants disagree with the Examiner's characterization of Runge and believe that these claims as previously pending are allowable over Runge, Applicants have amended Claims 1, 2, and 6 (from which Claim 9 depends) to expedite allowance of this application. Applicants reserve the right to pursue broader claims, e.g., Claims 1, 2, 6, and 9 as originally filed.

Runge

Runge is directed to a biventricular total cardiac support system that delivers blood into the ascending aorta for systemic circulation. The Runge system is shown in Figure 1, reproduced below.

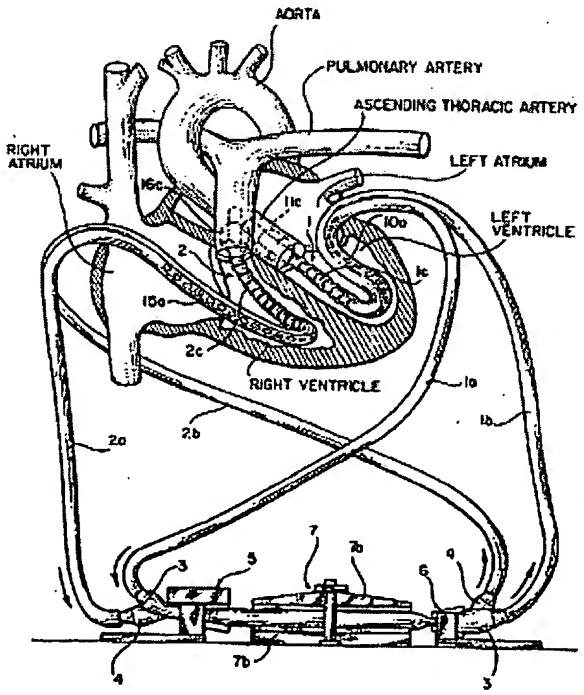
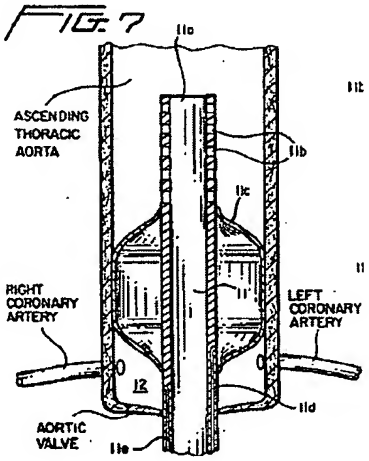


FIG. 1

The Runge system includes a two lumen cannula 1 that drains the left side of the heart and provides oxygenated blood for systemic circulation. Unlike the claimed invention, Runge does not teach or suggest, among other things, a redirecting tip positioned at a distal end of a lumen configured to redirect substantially all of the blood flow exiting the lumen in a direction generally opposite of the direction of flow in the lumen.

The cannula 1 has a pair of side-by-side lumens 10 and 11. A plurality of aspiration orifices 10a are provided in the side wall of the cannula 1, communicating with the lumen 10. The lumen 11 extends the full length of the cannula 1 and terminates at its distal end with a large end orifice 11a and a plurality of smaller orifices 11b in the side wall of the cannula 1 communicating with the lumen 11. An inflatable balloon 11c is positioned at the distal end portion of the lumen 11 below and adjacent to the side wall orifices 11b.

Figure 7, reproduced below, shows how the distal end of the cannula 1 is deployed in the ascending thoracic aorta.



The distal end of the cannula 1 is guided through the heart and through the aortic valve into the ascending thoracic aorta. Thereafter, the balloon 11c is inflated to anchor the cannula 1 in place. When in place, oxygenated blood in the left atrium and left ventricle drain through the orifices 10a into the lumen 10. The oxygenated blood is thereafter pumped into the lumen 11 and out through the large end orifice 11a and side wall orifices 11b, producing pulsatile flow of oxygenated blood in the aorta. In Runge, substantially all of the blood is directed distally out through the much larger orifice 11a and comparatively little blood will be directed through each of the side orifices 11b. Also, blood that exits the lumen 11 through the side wall orifices 11b would be directed substantially perpendicular to the lumen 11. Thus very little, if any, blood is redirected at the distal end of the lumen 11.

Moreover, the Runge device is expressly designed to *prevent* flow exiting the lumen 11 from being directed in a direction generally opposite of the direction of flow in the lumen. In the Runge system, the vasculature proximal of the orifices 11b, i.e., the coronary arteries, is perfused with a cardioplegia solution. If blood from the lumen 11 were redirected in the manner claimed, the cardioplegia solution would be diluted and would not function as intended. Furthermore, blood redirected out of the orifices 11b in the manner claimed would stagnate between the orifices 11b and the balloon 11c.

Claim 1

In contrast, Claim 1 recites multilumen catheter for directing the flow of blood through a patient through a single cannulation site, said catheter comprising:

> a catheter body having a proximal end, a first distal end, and a second distal end, said first distal end extending distally farther from the proximal end than the second distal end;
>
> a first lumen having a first cross-sectional area and extending between said first distal end and said proximal end;
>
> a second lumen extending between said second distal end and said proximal end and having a second cross-sectional area that is not substantially larger than the first cross-sectional area; and
>
> a redirecting tip positioned at the distal end of one of the lumens and configured to redirect substantially all of the blood flow exiting said lumen in a direction generally opposite of the direction of flow in the lumen.

Runge does not teach or suggest all of the limitations of Claim 1 set forth above. Therefore, Applicants respectfully submit that Claim 1 is patentably distinguished over Runge. Applicants respectfully request that the rejection of Claim 1 in view of Runge be withdrawn.

Claim 2

Similarly, Claim 2 recites, among other limitations, a multilumen catheter comprising "means for redirecting substantially all of the blood flow exiting [a] lumen in a direction generally opposite of the direction of flow in the lumen." Runge does not teach or suggest all of the limitations of Claim 2 set forth above. Therefore, Applicants respectfully submit that Claim 2 is patentably distinguished over Runge. Applicants respectfully request that the rejection of Claim 2 in view of Runge be withdrawn.

Claim 9

Claim 9 is a method claim that depends from Claim 6. Like Claim 1 and 2, Claim 6 is patentably distinguished over Runge. Claim 6 recites, among other limitations, a multilumen catheter comprising "a redirecting tip positioned at [a] distal end of [a] lumen[s] and configured to redirect substantially all of the blood flow exiting said lumen in a direction generally opposite of the direction of flow in the lumen . . . ."

Runge does not teach or suggest all of the limitations of Claim 6 set forth above. Therefore, Applicants respectfully submit that Claim 6 is patentably distinguished over Runge. As discussed above, Claim 9 depends from Claim 6 and further defines the invention thereof. Therefore, Claim 9 is patentably distinguished over Runge at least for the same reasons that Claim 6 is patentably distinguished over Runge. Applicants respectfully request that the rejection of Claim 1, 2, and 9 in view of Runge be withdrawn.

Claims 1, 2, 4, and 7-9 Are Patentably Distinguished Over Coleman et al.

Claims 1, 2, 4, and 7-9 are rejected in the Office Action as being anticipated under 35 U.S.C. § 102(b) as being anticipated by Coleman et al. (U.S. Pantent No. 5,928,181). The Examiner states that "Coleman teaches a two lumen catheter with a second lumen extending distally past the first lumen distal end and having a J-shaped tip." (Office Action, Page 2.) Although Applicants disagree with the Examiner's characterization of Coleman and believe that these claims as previously pending are allowable over Coleman, Applicants have amended Claims 1, 2, 6 (from which Claim 9 depends), 7, and 8 to expedite allowance of this application. Applicants reserve the right to pursue broader claims, e.g., Claims 7 and 8 as originally filed.

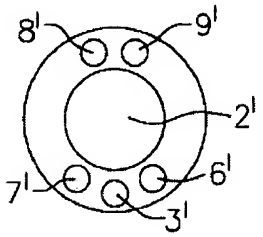
Coleman

Like Runge, Coleman is directed to a cardiac bypass catheter system. The system provides "artificial systemic blood circulation while temporarily arresting the heart and isolating the heart from systemic circulation." Column 1, lines 7-10. Figures 11-13 illustrate that in the Coleman system, separate arterial and venous catheter are deployed in the vasculature to form a blood circuit when the Coleman system is applied.

Figures 1A-8D show various arterial catheters for the Coleman system. An arterial catheter 1 illustrated in Figure 1A includes an elongate body 2. The elongate body 2 includes an internal flow lumen 2' (shown in Figure 1B). The arterial catheter 1 also includes a cardioplegia delivery port 8 and a ventricular venting port 9. The ports 8, 9 communicate with small lumens 8' and 9', shown in Figure 1B. The cardioplegia delivery port 8 is adapted to be positioned within the aortic root such that cardioplegia agent may be delivered to the heart via the coronary arteries stemming therefrom. As with Runge, the delivery port 8 must be located between the coronary arteries and an external shunt valve 3 to prevent the cardioplegia agent from migrating into the systemic vasculature. Column 13, lines 4-8. The ventricular venting port 9 is adapted to be positioned within the left ventricle and to aspirate blood from the left ventricle to create a substantially bloodless field during cardiac surgery when the heart is on bypass.

Figure 1B, reproduced below, illustrates that for the embodiment illustrated in Figure 1A, the lumen 2' is much larger than the lumen 8' and than the lumen 9'.

FIG. 1B



This feature found in each of the arterial catheter embodiments. One would not modify the Coleman arterial catheters making the cardioplegia and ventricular venting lumens similar in size to the lumen for infusing oxygenated blood because the blood-flow infusing lumen must provide physiologic circulation. In contrast, the cardioplegia and ventricular venting lumens only deliver or withdraw a comparatively small volume of fluid.

Claim 1, 2, and 4

In contrast, as discussed above, Claims 1 and 2 recite, among other things, a multilumen catheter comprising:

> a catheter body having a proximal end, a first distal end, and a second distal end, said first distal end extending distally farther from the proximal end than the second distal end;

a first lumen having a first cross-sectional area and extending between said first distal end and said proximal end;

a second lumen extending between said second distal end and said proximal end and having a second cross-sectional area that is not substantially larger than the first cross-sectional area . . . .

Coleman does not teach or suggest all of the limitations of Claims 1 or 2 set forth above. Therefore, Applicants respectfully submit that Claims 1 and 2 are patentably distinguished over Coleman. Applicants respectfully request that the rejection of Claims 1 and 2 in view of Coleman be withdrawn. Claim 4 depends from Claim 1 and further defines the invention thereof. Therefore, Claim 4 is patentably distinguished over Coleman at least for the same reasons that Claim 1 is patentably distinguished over Coleman. Applicants respectfully request that the rejection of Claims 1, 2, and 4 in view of Coleman be withdrawn.

Claim 7

Similarly, Claim 7 recites, among other things, a multilumen catheter comprising:

a catheter body having a proximal end, a first distal end, and a second distal end, said first distal end extending distally farther from the proximal end than the second distal end;

a first lumen extending between said first distal end and said proximal end adapted to fluidly communicate with the patient;

a second lumen extending between said second distal end and said proximal end adapted to fluidly communicate with the body independently of the first lumen; and

a third lumen in fluid communication with the second lumen, said second and third lumens being positioned radially around the first lumen in a housing that surrounds said first lumen, the combined cross-sectional area of said second and third lumens being not substantially different from the cross-sectional area of said first lumen.

Coleman does not teach or suggest all of the limitations of Claim 7 set forth above. Therefore, Applicants respectfully submit that Claim 7 is patentably distinguished over Coleman. Applicants respectfully request that the rejection of Claim 7 in view of Coleman be withdrawn.

Claim 8

Similarly, Claim 8 recites, among other things, a multilumen catheter comprising:

> a catheter body having a proximal end, a first distal end, and a second distal end, said first distal end extending distally farther from the proximal end than the second distal end;
>
> a first lumen extending between said first distal end and said proximal end adapted to fluidly communicate with the patient;
>
> a second lumen extending between said second distal end and said proximal end adapted to fluidly communicate with the body independently of the first lumen;
>
> a third lumen in fluid communication with the second lumen, said second and third lumens being positioned radially around the first lumen in a housing that surrounds said first lumen; and
>
> a fourth lumen in fluid communication with the second and third lumens, said second, third and fourth lumens being positioned symmetrically radially around the first lumen in a housing that surrounds said first, the combined cross-sectional area of said second, third, and fourth lumens being not substantially different from the cross-sectional area of said first lumen.

Coleman does not teach or suggest all of the limitations of Claim 8 set forth above. Therefore, Applicants respectfully submit that Claim 8 is patentably distinguished over Coleman. Applicants respectfully request that the rejection of Claim 8 in view of Coleman be withdrawn.

Claim 9

Claim 9 is a method claim that depends from Claim 6. Claim 6 is patentably distinguished over Coleman. Claim 6 recites, among other things, a multilumen catheter comprising:

> a catheter body having a proximal end, a first distal end, and a second distal end, said first distal end extending distally farther from the proximal end than the second distal end;
>
> a first lumen extending between said first distal end and said proximal end adapted to fluidly communicate with the patient;
>
> a second lumen extending between said second distal end and said proximal end adapted to fluidly communicate with the body independently of the first lumen; . . .
>
> wherein the second lumen is positioned coaxially with the first lumen . . .

Coleman does not teach or suggest all of the limitations of Claim 6 set forth above. Therefore, Applicants respectfully submit that Claim 6 is patentably distinguished over Coleman. As discussed above, Claim 9 depends from Claim 6 and further defines the invention thereof.

Therefore, Claim 9 is allowable at least for the same reasons that Claim 6 is allowable. Applicants respectfully request that the rejection of Claim 1, 2, 4, and 7-9 in view of Coleman be withdrawn.

Claim 6 Is Patentably Distinguished Over Aboul-Hson

Claim 6 are rejected in the Office Action as being anticipated under 35 U.S.C. § 102(b) as being anticipated by Aboul-hson (PCT Publication WO 99/59652). Although Applicants disagree with the Examiner's characterization of Aboul-hson and believe that Claim 6 as previously pending is allowable over Aboul-hson, Applicants have amended Claim 6 to expedite allowance of this application. Applicants reserve the right to pursue broader claims, e.g., Claim 6 as originally filed.

Aboul-hson

Aboul-hson is directed to a pulmonary and circulatory blood flow support device for use in connection with heart surgery procedures. Figure 1 illustrates the Aboul-hson pump and cannula system and its manner of application. A concentric cannula 120 is inserted into the right atrium 22 so that an outer conduit 123 is located in the right atrium 22. An inner conduit 121 is inserted through a tricuspid valve 32, pulmonary valve 33 and into the pulmonary artery 24. The arrows in Figure 1 indicate that blood is drawn into the outer conduit 123 and is pumped through the inner conduit 121 into the pulmonary artery 24 in the same direction in which it flow in the artery 24.

In contrast, Claim 6 recites, among other things, a multilumen catheter comprising:

> a catheter body having a proximal end, a first distal end, and a second distal end, said first distal end extending distally farther from the proximal end than the second distal end;
>
> a first lumen extending between said first distal end and said proximal end adapted to fluidly communicate with the patient;
>
> a second lumen extending between said second distal end and said proximal end adapted to fluidly communicate with the body independently of the first lumen; and
>
> a redirecting tip positioned at the distal end of one of the lumens and configured to redirect substantially all of the blood flow exiting said lumen in a direction generally opposite of the direction of flow in the lumen;. . . .

Aboul-hson does not teach or suggest all of the limitations of Claim 6 set forth above. Therefore, Applicants respectfully submit that Claim 6 is patentably distinguished over Aboul-hson. Applicants respectfully request that the rejection of Claim 6 in view of Aboul-hson be withdrawn.

Claims 10-17 Are Patentably Distinguished Over Rom

Claims 10-11, 13-15, and 17 are rejected in the Office Action as being anticipated under 35 U.S.C. § 102(b) as being anticipated by Rom et al. (U.S. Pantent No. 5,746,709). Claims 12 and 16 have been rejected under 35 U.S.C. § 103(a) as being obvious in view of Rom. The Examiner states that "Rom shows a multilumen tube with . . . a first lumen 42 and an inflation lumen stopping short at the balloon member." The Examiner also states that "with all valves open, the various lumens would be in fluid communication with the air." Applicants disagree with the Examiner's characterization of Rom and traverse these rejections.

Rom

Rom is directed to a intravascular pump and bypass assembly. Figures 1-3 illustrate that the Rom assembly includes a pump and balloon catheter assembly 12. The assembly 12 comprises a primary catheter 14 having a distal end 16 and a proximal end 18. The primary catheter 14 has a catheter body 32 and a balloon 34 provided on the exterior surface of the catheter body. One end of an inflation lumen 36 is fluidly connected to the balloon. A luer connector and stopcock valve 38 is provided on the other end of the lumen 36. The lumen 36 conveys fluid to the balloon 34 to inflate the balloon 34. A lumen 42 is formed in the catheter body 32, adjacent the distal end 16. Blood is pumped through the lumen 42 when the Rom assembly is used.

As discussed above, the Examiner asserts with "all valves open, the various lumens would be in fluid communication with the air" and therefore, presumably with each other. However, this is not what is meant by pending claim 10, wherein fluid communication is provided between two lumens of a multilumen catheter so as to supplement circulation. Applicants respectfully assert that there can be no circulation where fluid communication is only by way of two lumens communicating independently with air because blood exiting one lumen would not be conveyed in any manner, e.g., directly or otherwise, to the other lumen. Rather, blood exiting one of the lumens would be expelled from the system and lost.

In contrast, Claim 10 is directed to a system for supplementing circulation wherein at least two lumens of a multilumen catheter are in fluid communication with each other such that blood is conveyed from one lumen to another lumen. Rom does not teach or suggest at least these aspects of Claim 10. Therefore, Applicants respectfully submit that Claim 10 is patentably distinguished over Rom. Claims 11-17 depend from Claim 10 and further define the invention thereof. Therefore, Claims 11-17 are allowable at least for the same reasons that Claim 10 is allowable. Applicants respectfully request that the rejection of Claims 10-17 in view of Rom be withdrawn.

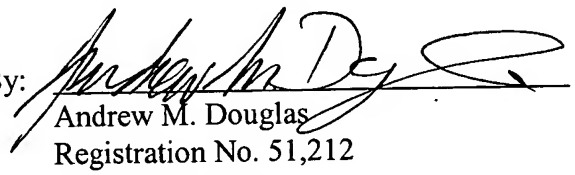
CONCLUSION

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance, and Applicants respectfully request that a Notice of Allowance be issued at the earliest opportunity.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 2, 2004

By: 

Andrew M. Douglas
Registration No. 51,212
Attorney of Record
Customer No. 20,995
(949) 760-0404

AMD-6274.DOC // 080204